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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,479	08/03/2001	R. Preston Mason	12915 P06	7261

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	10

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/921,479	Applicant(s) MASON, R. PRESTON	
	Examiner Dwayne C Jones	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-19,30-70,84 and 85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-19 and 30-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *39-70,84 and 85* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Claims

1. Claims 11-19, 30-70, 84, and 85 are pending.

2. Claims 11-19, and 30-38 are elected and rejected.

3. Claims 1-10, 20-29, and 71-83 are cancelled as per the amendment of June 24, 2003.

4. Claims 39-70, 84, and 85 are non-elected and withdrawn from consideration.

Election/Restrictions

5. This application contains claims 39-70, 84, and 85 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

6. Applicant's arguments filed June 24, 2003 have been fully considered but they are not persuasive. Applicant makes the following arguments. First, applicant alleges that the amended claims of the present invention recite the element of synergistically increasing nitric oxide production whereas Buch and Chang et al. do not teach of this allegation. Second, applicant argues that Buch and Chang et al. are silent to the functional recitations of inhibiting cholesterol formation and increasing the production of nitric oxide.

7. First, applicant alleges that the amended claims of the present invention recite the element of synergistically increasing nitric oxide production whereas Buch and Chang et al. do not teach of this allegation. Both Buch and Chang et al. teach of the very same composition that is comprised of both amlodipine and atorvastatin. Moreover, In addition, Buch teach of utilizing these pharmaceuticals for treating angina pectoris, atherosclerosis, combined hypertension and hyperlipidemia as well as patients with symptoms of cardiac risk, (see column 1, lines 4-23). Moreover, Chang teach of utilizing these pharmaceuticals for treating hypertension and hyperlipidemia, atherosclerosis, as well as patients with symptoms of cardiac risk, (see claims 9, 13 and 15).

8. Second, applicant argues that Buch and Chang et al. are silent to the functional recitations of inhibiting cholesterol formation and increasing the production of nitric oxide. Instant claims 11-19, and 30-38 are directed to composition claims. Both the prior art references of Buch and Chang et al. teach of the instantly claimed composition that is comprised of amlodipine and atorvastatin. In addition, because the HMG-CoA reductase inhibitor of atorvastatin is known to inter alia, reduce the level of blood cholesterol, it would obviously reduce the level of cholesterol formation since there would be less cholesterol to crystallize. Regarding applicant's allegation with the functional recitations of inhibiting cholesterol formation and increasing the production of nitric oxide, the courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art." Accordingly, the instant

invention is rendered obvious in view of each Buch and Chang et al. for both the above-stated and reasons of record.

Claim Rejections - 35 USC § 112

9. The rejection of claims 1, 2, 4, 6-12, 14, 16-21, 23, 25-31, 33 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification is withdrawn in response to the amendment of June 24, 2003.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. The rejection of claims 1-38 under 35 U.S.C. 103(a) as being unpatentable over Buch of U.S. Patent No. 6,455,574 is maintained and repeated. Buch disclose of pharmaceutical compositions that contain atorvastatin or its pharmaceutically acceptable salt, namely the hemicalcium salt of atorvastatin, and amlodipine along with its pharmaceutically acceptable salts, such as amlodipine besylate, (see abstract, column 5, lines 30-32, column 7, lines 49-52). In addition, Buch teach of utilizing these pharmaceuticals for treating angina pectoris, atherosclerosis, combined hypertension and hyperlipidemia as well as patients with symptoms of cardiac risk, (see column 1, lines 4-23). Although Buch does not specifically teach of inhibiting the crystal formation of cholesterol, it is well known in the art that HMG-CoA reductase inhibitors, in particular atorvastatin, are effective inhibiting HMG-CoA reductase

from catalyzing the rate-limiting step of cholesterol biosynthesis. Additionally, Buch is silent to increase in nitric oxide production by endothelial cells with the administration of the very same claimed compounds. However, in both of these instances, applicant is incorporating a functional recitation of a biochemical process. Accordingly, the skilled artisan would have been most certainly motivated to utilize the teachings of Buch to treat the very same ailments that are claimed by the instant invention. Moreover, it is well within the purview of the skilled artisan to utilize the prior art composition, as taught by Buch, in pharmaceutical preparations, which would inherently perform the functional recitations of inherent biochemical processes that occur with the administration of this previously taught compositions of atorvastatin, and amlodipine.

12. The rejection of claims 1-38 under 35 U.S.C. 103(a) as being unpatentable over Chang et al. of U.S. Patent No. 6,262,092 is maintained and repeated. Chang et al. disclose of pharmaceutical compositions that contain atorvastatin or its pharmaceutically acceptable salt, namely the hemicalcium salt of atorvastatin, and amlodipine along with its pharmaceutically acceptable salts, such as amlodipine besylate, (see abstract, claims 19 and 17). Moreover, Chang teach of utilizing these pharmaceuticals for treating hypertension and hyperlipidemia, atherosclerosis, as well as patients with symptoms of cardiac risk, (see claims 9, 13 and 15). Despite the fact that Chang et al. do not specifically teach of inhibiting the crystal formation of cholesterol, it is well known in the art that HMG-CoA reductase inhibitors, in particular atorvastatin, are effective inhibiting HMG-CoA reductase from catalyzing the rate-limiting step of

cholesterol biosynthesis. Additionally, Chang et al. are silent to increase in nitric oxide production by endothelial cells with the administration of the very same claimed compounds. However, in both of these cases, the applicant is attempting to incorporate a functional recitation of an inherent biochemical process. Accordingly, the skilled artisan would have been most certainly motivated to utilize the teachings of Chang et al. in order to treat the very same ailments that are claimed by the instant invention. Furthermore, it is well within the level of skill of the artisan to employ the prior art composition, as disclosed by Chang et al., in pharmaceutical preparations that would inherently perform the instantly claimed functional recitations because these biochemical processes that occur with the administration of this previously taught compositions of atorvastatin, and amlodipine, are inherent. Hence, the reference renders the instant invention obvious.

Obviousness-type Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

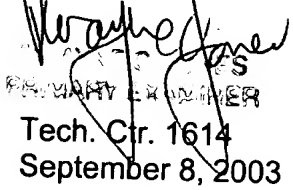
14. Claims 11-19, and 30-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 and 57-59 of copending Application No. 10/033,149. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications teach of compositions, which contain amlodipine and atorvastatin.

15. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



PRIMARY EXAMINER
Tech. Ctr. 1614
September 8, 2003